



"IF" Helicobacter Antigen Control (Non-sterile)



Article number : C0332

Intended Use :

"IF" Helicobacter Antigen Control is intended for quality control verification of *Helicobacter pylori* (*H. pylori*) antigen rapid test kits based on lateral flow immunoassay. The positive control liquid contains non-infectious antigens.

1. Test Principle

This product is used to confirm the performance of *H. pylori* antigen rapid test kits based on lateral flow immunoassay. When the "IF" Helicobacter Antigen positive control is added to the test kit, the solution moves on the test strip through diffusion. The sample well area of the test kit contains anti-*H. pylori* antibodies bound to colloidal particles. The positive control contains *H. pylori* antigens, which will form a complex with the *H. pylori* antibodies bound to the colloidal particles. This complex moves on the test strip and binds to the anti-*H. pylori* antibodies fixed on the test line (T) in the reaction area. Therefore, a red or pink line will appear on the test line (T). Conversely, the negative control does not contain *H. pylori* antigens, so there is no red or pink line will be produced on the test line (T). In each reaction, a red or pink line should appear on the control line (C).

2. Reagent

Article No.	C0332
Specification	"IF" Helicobacter Antigen Control ×1 set
Positive control	2 mL ×1
Negative control	2 mL ×1

3. Storage, Shelf Life

The kits are to be stored at 2 ~ 8°C. **DO NOT FREEZE!** The expiry date is indicated on the reagent bottles. Do not use the product after expiry date.

4. Material Needed but Not Supplied

Timer, *H. pylori* Antigen test kit, disposable gloves.

5. Test Procedure

- Before using the product, allow it to return to room temperature.
- Add 2 drops (approximately 80 µL) of control solution directly to the sample loading area of the kit.
- Follow the instructions for the *H. pylori* Antigen Test Kit.

6. Interpretation of Results

■ Positive Results (+)

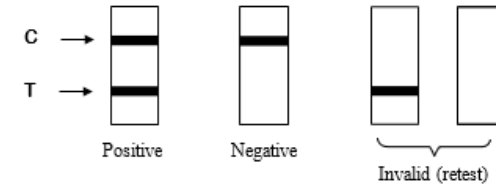
H. pylori antigen positive control : red/pink colored lines appear in the test line (T) and the control line (C).

■ Negative Results (-)

H. pylori antigen negative control : a red/pink line appears in the control line (C) and no red/pink line is visible in the test line (T).

■ Invalid (retest)

If no red/pink line appears in the control line (C), the test result is invalid, even if a red/pink line appears in the test line (T). A retest should be performed.



7. Precision

Intra-batch analysis and inter-batch analysis used the "IF" Helicobacter Antigen Control with "IF" Fecal Occult Helicobacter pylori Antigen Test, using 3 batches of the same negative and positive controls and repeated testing 15 times. The accuracy of the test results was above 99%.

⚠ Precaution

- This product is for professional in vitro diagnostic use only and is intended for use by medical professionals only.
- Do not use the product after expiry date.
- Do not eat, drink or smoke in sample handling area.
- All specimens should be treated as potentially infectious. During handling, established precautions for microbial hazards must be observed, and the standard procedures for proper specimen processing should be followed.
- When testing specimens, appropriate protective equipment such as laboratory coats and disposable gloves should be worn.
- After use, dispose the product and samples in accordance with applicable medical waste management guidelines.
- Improper storage conditions may affect the results.
- The product contains 0.1% sodium azide, avoid contact with eyes and mucous membranes. If contact occurs accidentally, rinse with water and seek medical attention immediately.
- The color intensity of the test line has no linear correlation with the antigen concentration in the specimen.
- Performance testing of this product was conducted using the "IF" Fecal Occult Helicobacter pylori Antigen Test and met the expectations results. Other comparable products should be independently verified to confirm their performance.

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